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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/623,485	09/15/2000	Nobuya Sato	197129US0PCT	7267
22850	7590	02/14/2005	EXAMINER	
OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.			GHALI, ISIS A D	
1940 DUKE STREET			ART UNIT	PAPER NUMBER
ALEXANDRIA, VA 22314			1615	

DATE MAILED: 02/14/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/623,485	SATO ET AL.	
	Examiner	Art Unit	
	Isis Ghali	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 26 January 2005.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,2 and 24-30 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1, 2, and 24-30 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____
4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

A final office action was issued by the office on October 15, 2004, applicants filed petition to withdraw the finality on November 04, 2004, and filed response after final on November 15, 2004. The petition has been granted by the director on January 26, 2005.

Hence, the finality of the previous Office action issued October 15, 2004 is hereby withdrawn. Applicant's amendment submitted after final on November 15, 2004 has been entered. A non-final office action on the merit is issued as follows.

Claim 3-23 have been canceled and claims 27-30 have been added.

Claims 1, 2, 24-30 are included in the prosecution.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1, 2, and 24-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The claims recite many thermoplastic resins that may vary in properties, such as low density and high density PE; and also broad classes of active ingredients that may act locally or systemically; as well as many oily ingredients including natural and synthetic oils and fats and their derivatives. Meanwhile, applicants did not provide enough guidance from the specification to enable one skilled in the art to practice the present invention without undue experimentation.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: the nature of the invention; the breadth of the claims; the state of the prior art; the relative skill of those in the art; the amount of direction or guidance presented; the predictability or unpredictability of the art; the presence or absence of working examples; and the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

The nature of the invention: The nature of the invention is complex as it is directed to a sheet comprising at least one thermoplastic resin selected from numerous genus, active agent selected from numerous genus, and oily ingredient selected from numerous genus and their derivatives.

The breadth of the claims: The complex nature of the claims is exacerbated by the breadth of the claims. The claims are very broad. The claims encompass wide

classes of each of the three components. The thermoplastic resin includes polyolefins, acrylics, polyesters, polyvinyl resins, polystyrenes, etc., and each one of these resins is a broad genus that encompasses huge number of species. The active agents include genus of many local and systemic drugs and numerous species and subspecies are under each category, e.g. anti-inflammatory drugs include steroidal and non-steroidal, and hundreds species and subspecies can be listed under this category alone. The oily ingredients include natural and synthetic fats and oils and also all the fatty acids and fatty alcohols and their esters and their derivatives.

The state of the prior art: The state of the art recognized sheet comprising polyolefin, hydrocarbon and inorganic filler, see US 3,725,520. The state of the art also recognized layer comprising EVA copolymer, glycerin and anti-wrinkling agent, US 6,180,133.

The relative skill of those in the art: The relative skill of those in the art is high.

The amount of direction or guidance presented: The specification provides no guidance, in the way written description, on sheet comprising each of the ingredients in terms of different combinations that can provides huge number of compositions. The specification does not enable all the claimed thermoplastic resins, all the oily ingredients and their derivatives and all of the active agents in their different combinations. It is not obvious from the disclosure if the combination of any of the claimed thermoplastic resins with any of the claimed fatty components will provide composition useful as a non-adherent sheet, and how the different combinations will affect each of the active agents that have different solubility and diffusability across the skin and hair. It is not clear from

the disclosure of few thermoplastic resins and few natural oils listed in tables 1-4 that all the claimed thermoplastic resins and all oils and fats and fatty acids and alcohols and their esters and derivatives will work. Further it is not clear from the disclosure that any of the claimed active ingredients will be delivered by the sheet applied to the skin or hair, e.g. slimming agent if applied to the skin or hair how it will cause slimming? The examples and comparative examples do not show any active ingredients in the combination of the oily ingredient and thermoplastic resin in order to show the effect of the sheet of the invention on the delivery of the active agents. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result." The article "Broader than the Disclosure in Chemical Cases," 31 J.P.O.S. 5, by Samuel S. Levin covers this subject in detail. A disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140 USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724.

The predictability or unpredictability of the art: The lack of guidance from the specification and from the prior art with regard to sheet comprising each of the three claimed components in different combinations makes practicing the claimed invention

unpredictable in the terms of which thermoplastic resin combined with which oily ingredient and which active agent would be effective as a non-adherent sheet that deliver active agent to the skin or hair.

The presence or absence of working examples: The specification has not enabled a reasonable amount of the possible combinations of the three ingredients of the composition, not even enabled any of the active agents. No working examples to show different combinations of the claimed components. Therefore, the specification has not enabled one skilled in the art to practice the invention without undue experimentation.

The quantity of experimentation necessary: Therefor, the practitioner would turn to trial and error experimentation to practice the instant sheet comprising three components without guidance from the specification or the prior art. Therefore, undue experimentation becomes the burden of the practitioner.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1, 2, 24-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The expression "derivatives" does not set forth the metes and bounds of the claim. Recourse to the specification does not define what are the derivatives of the glycerides that obtained from hydrogenation of natural fats and natural oils, or which

natural oils and which natural fats? What are the ester derivatives of higher alcohols higher fatty acids and what are those higher alcohols and higher fatty acids?

Claim 28 recites the limitation "thermoplastic elastomer (A)" in the phrase bridging first and second lines of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 2, 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 09-216809 ('809).

JP '809 teaches a cosmetic sheet having easy handability and applicable to the skin giving the attached area excellent benefit and excellent feeling free from stickiness to the skin (abstract). The sheet comprises polyvinyl alcohol especially vinylon (thermoplastic resin); oily ingredient including glycerol and fatty acid esters, natural oils, glyceride derivative which is hydrogenated natural oil, wax, paraffin microcrystalline wax, ceresin, and vaseline; and active agent selected from UV ray absorbent such as p-aminobenzoic acid glycerol, whitening agent, astringent, and anti-wrinkles agents (paragraphs 0016, 0024-0026, 0028, 0037, 0039, 0051, 0052). The sheet is made by blending the ingredient during the production of the sheet (paragraph 0059).

The reference does not teach the amounts of the different active agents, thickness of the sheet, or the modulus. It is within the skill in the art to select the amounts and thickness in order to achieve the required beneficial effect and physical properties, such as the modulus, according to specific intended use. Thus, the claimed amounts do not impart patentability to the claims since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a sheet comprising thermoplastic resin, active agent, and oily ingredient as disclosed by the reference, and manipulate the amount of the ingredients and the thickness of the sheet in order to achieve the desired beneficial

effects and physical properties of the sheet according to the intended use or site of application, with reasonable expectation of having a cosmetic sheet with desirable modulus that deliver active agents to the skin or hair with success.

Response to Arguments

8. Applicant's arguments filed 11/15/2004 have been fully considered but they are not persuasive. Applicants traverse that rejection by arguing that the reference teaches water-soluble non-woven fabric that washed from the skin by water, while the sheet of the present invention is not water soluble and removed by being peeled from the skin.

In response to this applicant's argument, it is noted that the features upon which applicant relies (i.e., the sheet is not water-soluble and being peeled from the skin) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the reference disclosed the same thermoplastic resins claimed by applicants, and they expected to have the same physical properties, such as solubility. Regarding the sheet is being peeled from the skin, it is functional properties on use of the sheet that does not impart patentability to claims directed to product or composition.

9. Claims 1, 2, 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 05-188527 ('527).

JP '527 teaches a cosmetic sheet used for conditioning and beautifying the skin that has excellent safety and stability (abstract). The sheet comprises polyhydric

alcohol, specially glycols such as low molecular weight PEG or propylene glycol, or polyacrylate; active agent such as anti-inflammatory agent, whitening agent, or circulation promoting agent, anti-oxidant (anti-aging), UV absorbent such as p-aminobenzoic acid ester or salicylate; and fatty ingredient such as sorbitan ester, glycerol esters or fatty acid ester (paragraphs 005, 0010, 0012, 0014, 0016, 0017, 0019). The method of making the sheet comprises the step of blending the ingredients and shaping the sheet (paragraphs 0021).

The reference does not teach the amounts of the different active agents, thickness of the sheet, or the modulus. It is within the skill in the art to select the amounts and thickness in order to achieve the required beneficial effect and physical properties, such as the modulus, according to specific intended use. Thus, the claimed amounts do not impart patentability to the claims since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide a sheet comprising thermoplastic resin, active agent, and oily ingredient as disclosed by the reference, and manipulate the amount of the ingredients and the thickness of the sheet in order to achieve the desired beneficial effects and physical properties of the sheet according to the intended use or site of application, with reasonable expectation of having a cosmetic sheet with desirable modulus that deliver active agents to the skin or hair with success.

Response to Arguments

10. Applicant's arguments filed 11/15/2004 have been fully considered but they are not persuasive. Applicants traverse that rejection by arguing that the reference teaches water-soluble polymeric fibers and the reference requires cross-linking agent, while the sheet of the present invention is not water soluble and does not require cross-linking.

In response to this applicant's argument, it is noted that the features upon which applicant relies (i.e., the present sheet is not water-soluble and not cross-linked) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Furthermore, the reference disclosed the same thermoplastic resins claimed by applicants, and they expected to have the same physical properties, such as solubility.

11. Claims 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of JP '809 or JP '527 in view of US 6,022,550 ('550).

The teachings of the references are discussed above, however, the references do not teach the thermoplastic elastomer claimed in claims 7-10.

US '550 teaches a sheet having shape-memory effect and excellent chemical resistance comprising polystyrene-based elastomer comprising hard styrene phase and flexible phase comprising diene compound such as polybutadiene (abstract; col.3, lines 56-61; col.4, lines 1-18, 26-33; col.5, lines 55-59).

Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide sheet comprising thermoplastic resin, active agent, and oily ingredient as disclosed by any of JP '809 or JP '527, and add the thermoplastic elastomer having hard styrene phase and flexible polybutadiene phase as disclosed by US '550, motivated by the teaching of US '550 that the sheet comprising this elastomer has shape-memory effect and excellent chemical resistance, with reasonable expectation of having a sheet comprising thermoplastic resin, active agent, oily ingredient and thermoplastic elastomer that can be used for medical purposes.

Response to Arguments

12. Applicant's arguments filed 11/15/2005 have been fully considered but they are not persuasive. Applicants' traverse that rejection by arguing that both JP references teach products based on water-soluble polymeric component, while the present invention thermoplastic resin is not water-soluble. US '550 does not germane to the present invention and the two JP references because it disclosed crosslinkable polymer composition used for molded articles that is fundamentally different from the sheet of the present invention that is applied to the skin or hair.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The arguments against the JP references regarding the water-soluble polymeric components are discussed above, i.e. applicants argue limitation not in the claims. JP

references teach sheet comprising thermoplastic resin, active agent and oily ingredient. US '550 is relied upon for teaching the thermoplastic elastomer currently claimed in claims 27-30. US '550 teaches elastomer (col.3, line 60) comprises hard phase and flexible phase as recited in the present claims 27-30. US '550 further teaches that the article can be molded to sheet or film that are applicable to the skin, as claimed by applicants. Therefore, the US '550 patent germane to the present invention and the two JP references because the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). The invention as a whole is taught by the combined teaching of the cited prior art.

In response to applicant's argument that the US '550 fails to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., non-crosslinked polymers) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The claim language permits the presence of cross-linking agents.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,880,044 teaches that vynylon is a thermoplastic resin, col.3, lines 45-47.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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